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## IN THE CLAIMS

Please cancel without prejudice claims 1, 3, 4, 7, 8, 11, (2), 13, 14, 22, 23, 25, 26 and 27.

Kindly amend the claims as follows.

Claim 2, line 1, replace "1" by --28--; line 2, insert --an-- before "anhydrous".

In line 1 of each of claims 6 and 12, replace "1" by --28--.

5 (amended). A Method according to claim [1] 28, which is characterised in that the nanodispersion comprises,

(a) as membrane-forming [molecules] molecule, substances which are suitable for forming bilayers,

(b) as [coemulsifiers] coemulsifier substances [which preferably form O/W structures] selected from the group consisting of emulsifiers of the polyoxethylene type, saturated and unsaturated C<sub>8</sub>-C<sub>18</sub>alkylsulfates, the alkali metal, ammonium or amine salts of C<sub>8</sub>-C<sub>20</sub>fatty acids, C<sub>8</sub>-C<sub>20</sub>alkanesulfonates, fatty alcohol phosphorates, the salts of colic acid, invert soaps; partial fatty acid esters of sorbitan, sugar esters of fatty acids, fatty acid partial glycerides, alkylmaltosides, alkylglucosides, C<sub>8</sub>-C<sub>18</sub>betaines, C<sub>8</sub>-C<sub>18</sub>sulfobetaines or C<sub>8</sub>-C<sub>24</sub>alkylamido-C<sub>1</sub>-C<sub>4</sub>alkylenebetaines, proteins, polyglycerol esters of fatty acids, propylene glycol esters of fatty acids and lactates of fatty acids, or a mixture of these substances, and,

(c) as lipophilic component, a [lipophilic] lipophilically active agent according to claim 28.

Claim 9, line 1, replace "8" by --28--.

Claim 15, line 1, replace "1" by --28-- and delete "end".

Claim 16, line 1, delete "end"; last line, replace "1" by --28--.

(amended). A pharmaceutical semisolid [end] formulation in the form of an ointment, [cream (O/W emulsions), rich cream (W/O emulsions),] oil-in-water emulsion, water-in-oil emulsion, gel, lotion, foam, paste, suspension, ovula or plaster, which comprises a nanodispersion as defined in claim [1]

Claim 18, line 1, delete "end"; last line, replace "1" by --28--.

Claim 19, line 2, replace the comma after "system" by or; last line, replace "1" by --28--.

In line 1 of each of claims 20, 21 and 24, delete "end".

Please add the following claims.

--28. A method of preparing a pharmaceutical formulation in the form of an aqueous nanodispersion, which comprises

- (a) mixing the components
  - (a) 0.1 to 30 % by weight of a membrane-forming molecule,
  - (b) 1 to 50 % by weight of a coemulsifier,
  - (c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic di- or triglyceride, a mineral oil, silicone oil, wax, fatty alcohol, guerbet alcohol or the ester thereof, a therapeutic oil, a lipophilic pharmaceutical active agent or a mixture of these substances, in which the lipophilic pharmaceutically active agent is always present as component
  - (c), and
  - (d) 0.63 to 14.2 % by weight of a C<sub>2</sub>-C<sub>8</sub>alcohol

in conventional stirring apparatus until a homogeneous clear liquid is obtained and

- ( $\beta$ ) adding the liquid obtained in step ( $\alpha$ ) to a water phase, wherein step ( $\beta$ ) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter <50 nm.
- 29. An aqueous nanodispersion, which comprises
  - (a) 0.1 to 30 % by weight of a membrane-forming molecule,
  - (b) 1 to 50 % by weight of a coemulsifier,
  - (c) 0.1 to 80/% by weight of a lipophilic component which is a natural or synthetic or a partially synthetic di- or triglyceride, a mineral oil, silicone oil, wax, fatty alcohol, guerbet alcohol or the ester thereof, a therapeutic oil, a lipophilic pharmaceutical active agent or a mixture of these substances, in which the lipophilic pharmaceutically active agent is always present as component (c), and
  - (d) 0.63 to 14.2 % by weight of a  $C_2$ - $C_8$ alcohol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight, plus

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(e) a water phase,

which formulation is obtainable by

- (a) mixing the components (a), (b), (c) and (d) until a homogeneous clear liquid is obtained, and
- ( $\beta$ ) adding the liquid obtained in step ( $\alpha$ ) to a water phase, wherein step ( $\beta$ ) is carried out in the absence of high shear or cavitation forces, and whereby the particles in the nanodispersion have an average diameter <50 nm.--

## STATUS OF THE CLAIMS

Claims 1-27 were pending in this application.

Claims 1-27 are rejected under 35 U.S.C. § 112, first paragraph.

Claims 1-27 are rejected under 35 U.S.C. § 112, second paragraph.

Claims 1-3, 5-13, 15-17, 20-21 and 25-27 are rejected under 35 U.S.C. § 102 as being anticipated by 5,171,566.

Claims 25-27 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,338,761 (Nakajima et al.).

Claims 1, 3, 4, 7, 8, 11, 12, 13, 14, 22, 23, 25, 26 and 27 have been cancelled.

Claims 2, 5-6, 9, 12, 15-21 and 24 have been amended and claims 28-29 have been added.

Claims 2, 5-6, 9-10, 12, 15-21 and 24 are presented for reconsideration; claims 28-29 are presented for consideration.

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